

METHOD FOR KEEPING THE QUALITY OF AQUEOUS PARENTERAL SOLUTION OF THROMBOMODULIN IN STORAGE AND DISTRIBUTION

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Abstract

A method for keeping the quality of an aqueous parenteral solution of thrombomodulin which is not in a frozen or freeze-dried state but in a liquid form in storage and distribution, characterized in that the aqueous thrombomodulin solution containing an effective amount of soluble thrombomodulin and a buffer component exhibiting a buffering activity in a pH range of 5 to 7.0 has a pH of 5 to 7.0 and that (a) the aqueous thrombomodulin solution further contains a surfactant and is in a state aseptically filled into a case or (b) the aqueous thrombomodulin solution is in the form of a prefilled syringe preparation produced by aseptically filling the thrombomodulin solution into a syringe substantially without any empty space. This method enables the storage and distribution of an aqueous parenteral solution of thrombomodulin in a liquid state for a prolonged period and makes it possible to provide an aqueous parenteral solution which is excellent in long-term stability and shaking stability and can save the trouble of dissolving in use.

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